CURRICULUM VITAE

ERVINA DWI ASTUTI

PERSONAL DATA:

N a m e : **Ervina Dwi Astuti**
Place/Date of Birth : Jakarta, 31 March 1984
Religion : Moslem
Marital Status : Married with two daughters
Permanent Address : Kav. PTB. Duren Sawit, Jln. Madrasah I Blok P/2
RT/RW 007/012 Jakarta Timur 13440
Phone : (021) 8615516 / 08128318097
Email address : ervina_dwiastuti@yahoo.com; ervina.dwiastuti@gmail.com

K E Y E X P E R I E N C E S & C O M P E T E N C I E S

- More than 16 years experiences on regulatory and quality activities in pharmaceutical and consumer health care industry
- Regulatory expertise with experience in managing Regulatory activities for Pharma, Vaccine and medical device
- Quality expertise with experience in managing country quality system that apply to GxP and health-regulated activities related to the distribution and commercialization of all products
- Experience in managing people from different function (Medical, Pharmacovigilance, Regulatory, IS, Procurement and GxP vendor) for Quality awareness
- Experience in handling product technical complaint
- Experience in managing Quality Risk Management issue and GxP Quality Audit
- Do Qualification to GxP vendors
- Good professional relationship with Health Authorities

E M P L O Y M E N T

- Taking internship program in *Departemen Kesehatan Republik Indonesia, Direktorat Jenderal Bina Kefarmasian dan Alat Kesehatan* at *Direktorat Bina Penggunaan Obat Rasional (*05-16 February 2007)
- Taking internship program in PT. Aventis Pharma at Industrial Quality and Compliance Department (March-April 2007)
- Taking internship program in *Apotek Sukma Sakti*, Jakarta (May-June 2007)
- PT. Bayer Indonesia as *Microbiology Laboratory Pharmacist* from 01 November 2007 until 14 May 2008
- PT. Aventis Pharma as *Regulatory Affairs Executive* from 15 May 2008-31 December 2011
- PT Aventis Pharma as ***Regulatory & Affiliate Quality Manager and Anti Counterfeit coordinator*** from 01 January 2012-31 August 2016
- PT Aventis Pharma as ***Country Quality Head*** from 01 January 2016-30 November 2017
- PT Aventis Pharma as ***Sr Regulatory Manager*** from 01 December 2017-28 February 2023
- PT Kalventis Sinergi Farma as ***Sr Regulatory Manage***r from 01 March 2023-30 January 2024
- PT Abbot Indonesia as ***Lead of Regulatory Affairs and Quality Commercia and as back up Affiliate Safety Representative*** from 31 January 2024-current

JOB DESCRIPTION

Current:

Core Job Responsibilities:

- Lead development of strategy & direction of regulatory affairs based on company objectives & evolving regulatory environment, which aligned as per global & APAC guidance, company policies and legal aspect.
- Identify regulatory opportunities and find innovative ways to address and mitigate regulatory risks.
- Develop and maintain positive relationship with all stakeholders either internal or external including key opinion leaders and key influencers in regulatory bodies & industry associations while building Abbott EPD's credibility and trust.
- Provide input into developing Abbott EPD's positions for regulatory and commercial quality assurance on emerging issues and implement plans to respond, influence or mitigate.
- On-time submission and approval of best-in-class regulatory documentation (including product submissions/re-registrations, novel ingredient applications, additive petitions, claims petitions and deficiency responses, etc); analysis and identification of regulatory requirements against project needs.
- Provide timely & up to date information on current regulations & laws to ensure all stakeholder (internal and external) are kept abreast and can act accordingly
- Partner marketing, sales, finance & manufacturing and provide regulatory direction and advice
- Manage Commercial Quality System within EPD ID, including training, supplier qualification, internal audit, management review.
- To oversee promotional material review & approval process.
- As a ASR back-up fulfils following responsibilities:
- Acts as Affiliate Safety Representative (ASR) back-up
  - ✓ Maintenance of the Affiliate PV System Country Chapter and additional local PV procedures, forms, and templates
  - ✓ PV business continuity planning and notification of any business interruptions that pose a threat locally or globally to pharmacovigilance processes or endanger regulatory compliance
  - ✓ Receipt, recording, and reconciliation of safety information
  - ✓ Safety surveillance including literature and health authority website screening and preparation of local periodic safety reports and Risk Management Plans
  - ✓ Regulatory submission of safety information
  - ✓ Basic PV training of local EPD staff
  - ✓ PV record retention and archiving
  - ✓ Implementation of out-of-office coverage for receiving and recording safety-relevant information
  - ✓ Maintenance of local PV product list
  - ✓ Ensure PV matters in local interventional studies and local non-interventional organized data collection schemes
  - ✓ Negotiation and implementation of local commercial pharmacovigilance agreements and local pharmacovigilance service agreements
  - ✓ Due Diligence for product acquisition or in-licensing negotiated by an Affiliate organization
  - ✓ Provision of local PV Compliance metrics and management of non-compliances
  - ✓ Coordination/management of PV audits and inspections at the Affiliate level
  - ✓ Perform vigilance compliant to local legislation for Abbott EPD products beyond medicinal products such as medical devices and food supplements
  - ✓ Support in preparation of Health Hazard Assessment/Medical Expert Statements
  - ✓ Perform PV quality checks requiring four-eye review

Previous as Sr Regulatory Manager

- Accountable to ensure that regulatory activity is submitted and approved in due time
- Develop relations with key regulatory authorities at a country level; discuss issues and find solutions in the best interests of company.
- Analyses and communicates any changes in the regulatory area and liaises with pertinent functions to ensure implementation of new ways of working as per need.
- Participates and contributes to the definition and implementation of strategies to prepare external regulatory environment to accommodate innovation
- Provide regulatory expertise and ensuring total compliance with legal requirements and ethical norms
- Ensures that execution at local level of regulatory strategy to maximize attendance of commercial strategies
- Collaborates with other Global Regulatory function to ensure dossiers submitted to HA are maintained and updated in line with current regulatory standards and legal requirements
- Manages portfolio rationalization activities
- Manages Promo and non-promo material approval, product strategies discussion and implementation, regulatory input – trends and competitors intelligence – in Brand teams
- Be responsible for regulatory risk assessment and management.
- Ensure Regulatory support for product crisis (shortages, discontinuation, counterfeit, recalls)
- Develop and manage Regulatory-related SOP.

Previous position Country Quality Head

- Define, implement and maintain a Country Quality system applying to GxP and health-regulated activities related to the development, distribution and commercialization of all products under development or marketed
- Enhance Quality culture & promote Quality mindset into the country governance, working principles and ways of operating
- Ensure appropriate communication of key messages pertaining to quality across the country organization, highlighting their possible business impact
- Lead and coordinate a network of professionals designated in each country function involved in GxP and health-regulated activities and embark them to address all matters related to quality
- Assure that a process for management of GxP documents and records is in place in all GxP and health-regulated areas, considering data integrity principles
- Ensure of good Country Quality audits and GxP regulatory inspections:
- Carry-out an annual Country Quality Review and organize the related meeting to present the outcomes to Country Senior Management Board
- Define and implement a process to manage deviations and CAPAs related to all GxP and health-regulated activities including those related to audits and inspection findings, across the country in a consistent manner, and train concerned associates accordingly
- Quality oversight of locally managed GxP subcontractors: ensure an appropriate quality oversight process of locally managed subcontractors for all GxP and health-regulated activities, either directly or through coordination with the concerned country functions (as appropriate)
- Handling product complaint, product-related quality events and other quality task, where applicable

E D U C A T I O N

FORMAL EDUCATION:

- Senior High School 12. Jakarta, graduated in 2002
- Bachelor Degree of Pharmacy, graduated in 2006
- Apothecary program, Pharmacy Department, University of Indonesia, graduated in 2007 with Cum laude

NON-FORMAL EDUCATION:

- Advanced Levels for General English, *Lembaga Bahasa & Pendidikan Profesional LIA*, Jakarta (2002/ Certificate)
- Computer Course (Microsoft Office), *Lembaga Bahasa & Pendidikan Profesional LIA,* Jakarta *(*2003/ Certificate)
- Conversation Course, *Lembaga Bahasa & Pendidikan Profesional LIA,* Jakarta (2007/Certificate)
- Conversation Course, *EF (English First),* Jakarta (2009/Certificate)

COMPUTER LITERACY:

Familiar in using/operating PC with MS Office Environment i.e.: MS Word, Excel, PowerPoint

PROFESSIONAL EXPERIENCES:

- Seminar "*Optimalisasi Peran Apoteker Dalam Pelayanan Informasi Obat Pada Pasien Penderita Penyakit Kronis (Kardiovaskular & Diabetes Mellilus)"* (2005 / Certificate)
- Seminar "*Trend Perkembangan Perusahaan Farmasi di Era Mendatang*" (2007 / Certificate)
- Committee of Seminar "*Tantangan Farmasi Dalam Menghadapai Dunia Kosmetik dan* Cosmeceutical" (2007 / Certificate)
- Seminar "*Enterpreunership dan Etik Kerja*" (2007 / Certificate)
- Pharmacovigilance Training of Sanofi aventis
- Seminar " Penataran Uji Kompetensi Apoteker" (PUKA) (2009 / Certificate)
- Training "Problem Solving and Decision Making*"* at Prasetiya Mulya Jakarta (2009/ certificate)
- Training Pharmacovigilance in PT Aventis Pharma (2008)
- Getting "Asia Pacific Medical Excellence Award" (2009/certificate)
- Training "Dynamic and Persuasive Business Communication" at LP3i Jakarta (2010/certificate)
- Evaluation "*Kemampuan Industri ALKES dalam penerapan Formulir Ijin Edar sesuai CDST*" (19 November 2010) by Ministry of Health
- Training e-learning Module "Product Alert e-learning module", 2 August 2011/certificate by Sanofi Global
- Training "Supervisory Acceleration Series" (20-21 September 2011/certificate) by Daya Dimensi Indah
- Seminar "ACCSQ Medical Device" in Hanoi Vietnam (10-14 October 2011) by ASEAN
- Training "The diabetes medico-marketing meeting" in Singapore (13-15 March 2012) by Sanofi
- Seminar "Sanofi Anti Counterfeit Convention*"* in Paris (22-24 May 2012) by Sanofi

- Seminar “ACCSQ Drug Product” in Bangkok Thailand (2-6 July 2012) by ASEAN
- Training : “Global Pen Training” in Singapore (19-20 September 2012/certificate) by Sanofi
- Getting “Asia Medical Excellence Award “ (2012/certificate)
- Seminar “Affiliates and Distribution Asia Pacific Japan Global Quality Days” (27-29 November 2012) by Sanofi
- Training “Audit Qualification” (27-29 November 2012/certificate)) by Sanofi
- Training “Empowerment of The Black- Belt Team (31 October 2013/certificate) by Sanofi
- Seminar “ *Sertifikasi Kompetensi Apoteker*” (21 December 2013) by Ikatan Apoteker Indonesia
- Training “ Drug Registration and Evaluation Course & Workshop “(24-25 February 2014) by Clinical Study Unit, Medicine Faculty, University of Indonesia
- Annual Conference ISPE Indonesia (May 2016) in Holiday Iin, Kemayoran, Jakarta
- Training Halal (May 2016) in Jakarta by LPPOM MUI
- Training *“*How to manage Pharma Warehouse in compliance with GMP and GDP*”* (June 2016) by ISPE
- Training “Knowing me, Knowing you, Knowing us” (July 2016) Training by PACE
- Training *“*Good Clinical Practice*”* in August 2016 by Respina in Indonesia
- Training *“*How to manage Pharma Warehouse in compliance with GMP and GDP*”* (June 2016) by ISPE
- ISPE Indonesia Affiliate Annual Conference (May 2017) by ISPE
- Halal Training by LPPOM MUI in April 2017
- International Halal Bogor on Halal Assurance System by LPPOM MUI in October 2017
- Time Management Training by Sanofi Internal in April 2019
- Training “Safety Assessment of Cosmetics (Introduction)” by Pendidikan Kedokteran Berkelanjutan Farmakologi & Terapeutik Yayasan Pengembangan Farmakologi & Terapeutik UI in April 2019
- Seminar “*Rakernas dan Pertemuan Ilmiah Tahunan IAI*” by Ikatan Apoteker Indonesia in 05-07 November 2020
- Training “Influencing Skill & Effective Communication” in 05 February 2021
- Seminor “Pharmaceutical and Health Care Virtual Summit” in 27-29 May 2021

PROJECTS HANDLED

- Second Brand Registration
- Transfer to local Manufacturing product Project related with Decree 1010 Regulation in Indonesia
- Repatriation Marketing Authorization Project
- Involve in Name Patient Program and SAS project for some rare disease products
- Coordinator Lead of Preparation GxP Audit for Medical, PV, Quality, Regulatory, Supply Chain part
- Halal Project as Halal Leader in 2016-mid of 2018
- Involved in 2D barcode Project
- Vaccine neutral box project

I certify that the above statements are true, complete and correct to the best of my knowledge and belief.

Yours sincerely,

Ervina Dwi Astuti